TPS4153 General Poster Session (Board #32G), Sun, 8:00 AM-11:45 AM

RILOMET-1: An international phase III multicenter, randomized, double-blind, placebo-controlled trial of rilotumumab plus epirubicin, cisplatin, and capecitabine (ECX) as first-line therapy in patients with advanced MET-positive gastric or gastroesophageal junction (G/GEJ) adenocarcinoma.

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Background: Rilotumumab is an investigational, fully human monoclonal antibody to hepatocyte growth factor/scatter factor that inhibits signaling through the MET receptor. In a randomized phase II study in patients with advanced G/GEJ adenocarcinoma, addition of rilotumumab every 3 weeks (Q3W) to ECX showed trends toward improved overall survival (OS) and progression-free survival (PFS) compared with ECX alone. In patients with high tumor MET expression and high rilotumumab exposure, the treatment effect of rilotumumab combined with ECX was significantly enhanced. **Methods:** In this phase III study, patients (planned N=450) are randomized 1:1 to ECX (intravenous [IV] epirubicin 50 mg/m^2 on day 1, IV cisplatin 60 mg/m^2 on day 1, and oral capecitabine 625 mg/m^2 twice daily on days 1−21) plus double-blind rilotumumab 15 mg/kg or placebo IV Q3W. Randomization is stratified by disease extent (locally advanced vs metastatic) and Eastern Cooperative Oncology Group (ECOG) score (0 vs 1). Key eligibility criteria include previously untreated, pathologically confirmed unresectable locally advanced or metastatic G/GEJ adenocarcinoma; ECOG score 0 or 1; ≥18 years old; MET-positive by centralized immunohistochemistry; HER2-negative; adequate organ function; and ≥6 months since neoadjuvant/adjuvant therapy. The primary endpoint is OS. Key secondary endpoints include PFS, 12-month survival rate, objective response, OS in MET expression tertiles, safety, and pharmacokinetics. An exploratory objective is to assess associations between outcomes and tumor and circulating biomarkers. Enrollment began in November 2012, and the trial continues to accrue. An independent data monitoring committee will conduct planned interim reviews for safety and efficacy. Status: recruiting participants. Sponsored by Amgen Inc. Clinical trial information: NCT01697072.